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PATENT
ATTY. DOCKET NO. L-F/104H

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Niehoff
Serial No. : 09/307,633
Filed : May 7, 1999
For : SYRINGE WITH INDICIA FOR CONTROLLING PLUNGER DRIVE (AS AMENDED)

Art Unit: 3763
Examiner: J. Maynard

Assistant Commissioner of Patents
BOX: AF FEE
Washington, DC 20231

TRANSMITTAL OF APPEAL BRIEF

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on February 15, 2006.
2. STATUS OF APPLICANT

This application is on behalf of:

- ☒ Other than a Small Entity
☐ Small Entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
☐ Enclosed is a verified statement to establish Small Entity status

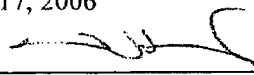
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Re: Our File: L-F-104H
US Application Serial No. 09/307,633
Filed May 7, 1999
CONTROLLING PLUNGER DRIVES
FOR FLUID INJECTIONS IN
ANIMALS
Niehoff

Pages: 23 (including cover sheet)

MESSAGE/COMMENTS

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PATENT
ATTY. DOCKET NO. L-F/104H

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte Niehoff

Appeal No. _____

Serial No.: 09/307,633
Filed: May 7, 1999
Group Art Unit: 3763
Examiner: J. Maynard
Applicant: Niehoff
Title: CONTROLLING PLUNGER DRIVES FOR FLUID
INJECTIONS IN ANIMALS

Cincinnati, Ohio 45202

April 17, 2006
Via Facsimile

APPEAL BRIEF


This brief is in furtherance of Applicant's Notice of Appeal filed February 15, 2006, appealing the decision of the Examiner dated November 15, 2005 finally rejecting claims 22, 24, 26, 28 and 30. A copy of the claims appears in the Appendix to this brief.

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Thomas W. Humphrey
Reg. No. 34,353

April 17, 2006
Date

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Real Party In Interest

The real party in interest in this appeal is Liebel-Flarsheim Company, a corporation of Delaware having a place of business at 2111 East Galbraith Road, Cincinnati, OH 45237.

Related Appeals and Interferences

There are no such appeals or interferences.

Status of Claims

Claims 22, 24, 26, 28 and 30, stand rejected and claims 23, 25, 27, 29 and 31 are found allowable but objected to for being dependent upon a rejected base claim.

Claims 1-21 were originally filed with the application. Applicant filed a Preliminary Amendment with the application dated May 7, 1999, wherein claims 1-21 were deleted and new claims 22-31 were added. In the Response to Office Action filed May 24, 2000, Applicant amended claims 22, 24, 26, 28 and 30. Applicant filed an Amendment for Appeal on May 30, 2001 wherein claims 22, 24, 26, 28 and 30 were amended. In a further Amendment for Appeal filed October 23, 2001, claim 24 was amended. A Request for Continued Examination was filed together with an Amendment on April 23, 2003, wherein claims 22, 24, 26, 28, 30 and 31 were amended. A Response to Office Action was filed on November 3, 2003, and claims 22-31 were amended. Responses to Office Actions were filed on July 21, 2004 and on August 9, 2005, with no claim amendments being made in either.

Status of Amendments

There are no amendments pending.

Summary of Claimed Subject Matter

The present claims recite novel concepts relating to the control of a medical injector. Specifically, each claim recites an empty syringe and a pre-filled syringe. An empty and a pre-filled syringe can be respectively seen in Figs. 1A and 1B; in these, the pre-filled syringe includes an extender for extending the plunger, which is a feature recited by the allowed dependent claims. The independent claims do not recite or require such an extender.

As recited in each independent claim, at least one of the recited empty and pre-filled syringes, bears “physical indicia” that can be read by an injector to determine various specific parameters about the syringe. These parameters include the “capacity of said syringe” (claim 22), “distance of the plunger from an end of said syringe when said syringe is initially installed on an injector” (claim 24), “information related to the amount of fluid pre-filled in the pre-filled syringe” (claim 26), an “end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector” (claim 28), and the “range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector” (claim 30).

An injector able to read this information from a syringe is thereby capable of controlling an injection, in a manner appropriate to an installed syringe, with minimal manual manipulation by the technician responsible for the injector.

Grounds of Rejection

Claims 22, 24, 26, 28 and 30 stand rejected under 35 U.S.C. 103, asserted to be unpatentable over Reilly (US Patent 5,383,858) in view of Applicant's disclosure, or in view of Stade (US Patent 4,636,198). In this rejection reference is also made to Hyde (US Patent 2,966,175).

Claims 22, 24, 26, 28 and 30 also stand rejected under 35 U.S.C. 103, asserted to be unpatentable over Stade in view of Reilly. In this rejection reference is also made to Hyde.

Claims 22, 24, 26, 28 and 30 also stand rejected under 35 U.S.C. 103, asserted to be unpatentable over Fenton (US Patent 4,652,260) in view of Stade.

Argument

On the merits, the Examiner has initially asserted that all claims are obvious in view of Reilly et al. '858 in view of Stade '198 or alternately obvious in view of Stade '198 in view of Reilly et al. '858. Applicant respectfully strongly disagrees with this rejection.

The Examiner's rejections are premised upon the Examiner's interpretation of Reilly et al. '858 as teaching "physical indicia (70/70b/70s) interacting with the injector on one of the syringes indicating information related to the capacity of the syringe, i.e. the dimensions of the syringe, the content (defined as the amount of specified material contained, see Merriam Webster's Collegiate Dictionary (tenth edition) (c) 1997, "content on page 250) of the syringe in the case of a pre-filled syringe, manufacturing information, recommended contrast media flow rates/pressures, and loading/injection sequences, see Column 6, lines 45-51."

The Examiner relies upon Stade as showing a power syringe with a volume reducing adapter much like that seen in Fig. 1B of the present application, which the present application identifies as a "typical pre-filled syringe".

The Examiner acknowledges that Stade, and the background discussion in Reilly, "fail[] to disclose a physical indicia interacting with the injector on the syringe indicating information related to the capacity of the syringe." Thus, the Examiner's rejection hinges upon her interpretation of Reilly et al. '858 as showing indicia on a syringe related to the capacity of the syringe. Applicant submits that there is no such disclosure in Reilly et al. '858.

The language in Reilly col. 6, lines 45-51 that the Examiner relies upon reads as follows:

"Examples of the information which could be encoded on the encoding device 70 include dimensions of the syringe 22, content of the syringe in the case of a pre-filled syringe, manufacturing information such as lot numbers, dates and tool cavity number, recommended contrast media flow rates and pressures, and loading/injection sequences."

This language does not suggest encoding information relating to the capacity of the syringe onto indicia.

As an initial matter, it should be observed that Reilly '858 nowhere discusses or illustrates syringes of different capacities. Indeed, even in its references to "pre-filled" syringes, there is no suggestion that the syringes might be "partially" pre-filled, or that some (pre-filled or empty) syringes would have different capacities than others. Thus, there is no context in the Reilly et al. '858 patent that would lead toward syringes with different capacities.

Turning, then, to the specific language of col. 6, Applicant notes that the Examiner's interpretation appears to focus (using a dictionary definition) on the reference to "content of the syringe in the case of a pre-filled syringe". The other "information" is rightly discarded: "Dimensions of the syringe 22" does not reference a changing capacity; indeed, it appears to refer to syringe wall thickness and strength, which relates to "recommended contrast media flow rates and pressures", as well as to maximum injection pressure as discussed in the immediately following paragraph (bridging columns 6 and 7). Similarly, "Manufacturing information such as lot numbers, dates and tool cavity number" and "loading/injection sequences" also do not refer to a changing syringe capacity.

As to "content of the syringe in the case of a pre-filled syringe", Applicant submits that the language "in the case of a pre-filled syringe" included in this phrase reveals that "content"

does not refer to the capacity of the syringe, but rather to the kind of pharmaceutical in the syringe. If, as the Examiner theorizes, "content" referred to the "capacity" of the syringe, it would be irrelevant whether the syringe were filled or empty – filling (or pre-filling) a syringe does not change its "capacity". But as the quoted phrase from Reilly et al. '858 makes clear, "content" is only of interest "in the case of a pre-filled syringe"; Applicant submits that the Examiner's theory is thus incorrect. "Content" is only relevant "in the case of a pre-filled syringe" because "content" refers to what is "pre-filled", i.e., what pharmaceutical is in the syringe. Indeed, this is the typical meaning of "content" and the first definition of "content" on page 250 of the Examiner's dictionary: the "something [pharmaceutical] contained" in the syringe is its "content". "Content" is thus not capacity.

Accordingly, Applicant submits that Reilly et al. '858 does not, in fact, disclose "physical indicia interacting with the injector on the syringe indicating information related to the capacity of the syringe", and as the Examiner admits that Stade '198 also fails to disclose this concept, Applicant submits that all claims are allowable over Reilly and Stade, regardless of the order in which they are combined, as both fail to teach each element of the invention claimed.

The Examiner's Final Action also rejects Applicant's claims by reference to Fenton. Fenton discloses an injector in which a connector 126 is mounted on a syringe 20 as shown in Fig. 12, and then the syringe and connector are mounted in the injector. The connector is mounted in different ways when it is used with different syringes. As noted at col. 7 line et seq.:

The position of the connector 126 in the infusion device 10 is determined by the size of the syringe 20. For smaller syringes (e.g., those of 10 cc and 20 cc capacity), the entire connector 126 will be inside the infusion device, and only the flexible tubing 30 will extend through the slot 28 at the front of the device 10 (see FIG. 4). For larger and longer syringes (e.g., those of 30 cc capacity), a portion of the connector 126 will extend through the slot 28 (see FIG. 3). Accordingly, the starting point for the plunger driver 32 will be approximately the same regardless of the size of the syringe 20. Furthermore, detection of the position of the connector 126 in the infusion device 10 will determine whether small or large syringes are in the device. In some cases, smaller syringes may be emptied at higher speeds than larger syringes, with the position of the connector being used to control the speed of the drive motor assembly 52, as will be seen below.

The disclosure of Fenton describes detecting the position of the connector via a microswitch or an optical detector.

The Examiner posits that Fenton teaches the claimed invention when combined with Stade.

With respect, Applicant submits that this rejection is clearly in error as Fenton does not disclose, as recited, “physical indicia ... on one said syringe indicating information” as is recited in each of the rejected claims. Rather, Fenton discloses a connector that is attached to a syringe, not any “indicia” on the syringe itself. The syringes shown by Fenton are not described as including indicia, rather, the type of the syringe is identified by the position of the connector in the injector. Notably, Fenton uses the same connector on each syringe, therefore, the connector cannot “indicate information ...” of the kind identified in the claims, as the connector is the same, regardless of the syringe on which it is mounted.

The Examiner is attempting to draw an analogy between the connector 126 and the “physical indicia” recited in the claims, but this analogy fails because there is no difference between the connector used by Fenton with large syringes and the connector used with small

syringes – the connector is the same. Thus, the connector does not and is not capable of indicating anything about the syringe to which it is attached. Thus, again, there is no disclosure of “physical indicia” having the properties recited in the claims.

The Examiner’s Final Rejection makes reference to Hyde, but does not explicitly use that patent in a rejection. Applicant is uncertain what aspect of this 1960 patent is of relevance to the present invention, and is unable to identify any “support for providing volume and capacity indicia on syringes” as posited by the Examiner at the locations cited in Hyde, or at other locations. Applicant would appreciate clarification of the Examiner’s use of Hyde point so that it can be addressed in Applicant’s reply brief, if necessary.

In view of the foregoing, Applicant submits that the Examiner's rejection is in error and a reversal of the rejection and allowance of the claims is therefore requested.

Respectfully submitted,
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Claim Appendix

Claims 1-21 have been canceled.

22. (Previously presented) An empty syringe and a pre-filled syringe, the syringes respectively comprising

a body having a closed forward end having a nozzle and an open rearward end, the body of each syringe having a common diameter, and including structure mountable in a common injector,

a plunger located within said body,

said empty syringe having a first capacity,

said prefilled syringe being prefilled to capacity with an amount of fluid different than said first capacity, and

physical indicia interacting with said common injector on one said syringe indicating information related to the capacity of said syringe.

23. (Previously presented) The empty and pre-filled syringes of claim 22 wherein said physical indicia represents the length of an extender which is attached to said plunger within said prefilled syringe.

24. (Previously presented) An empty syringe and a prefilled syringe, the syringes respectively comprising:

a body having a closed forward end having a nozzle and an open rearward end, the body of each syringe having a common diameter, and including structure mountable in a common injector,

a plunger located within said body,

said empty syringe having a first capacity,

said prefilled syringe being prefilled to capacity with an amount of fluid different than said first capacity, and

physical indicia interacting with said common injector on one said syringe indicating information related to the distance of the plunger from an end of said syringe when said syringe is initially installed on an injector.

25. (Previously presented) The empty and pre-filled syringes of claim 24 wherein said physical indicia represents the length of an extender which is attached to said plunger within said prefilled syringe.

26. (Previously presented) An empty syringe and a pre-filled syringe, the syringes respectively comprising

a body having a closed forward end having a nozzle and an open rearward end, the body of each syringe having a common diameter, and including structure mountable in a common injector,

a plunger located within said body,

said empty syringe having a first capacity,

said pre-filled syringe being pre-filled with an amount of fluid different than said first capacity, and

physical indicia interacting with said common injector on said pre-filled syringe indicating information related to the amount of fluid pre-filled in the pre-filled syringe.

27. (Previously presented) The empty and pre-filled syringes of claim 26 wherein said physical indicia represents the length of an extender which is attached to said plunger within said pre-filled syringe.

28. (Previously presented) An empty syringe and a pre-filled syringe, the syringes respectively comprising

a body having a closed forward end having a nozzle and an open rearward end, the body of each syringe having a common diameter, and including structure mountable in a common injector,

a plunger located within said body,

the empty syringe having a first capacity,

said pre-filled syringe being prefilled with an amount of fluid different than said first capacity, and

physical indicia interacting with said common injector on one said syringe indicating information related to the end of travel position of an injector ram coupled to the plunger when the syringe is coupled to an injector.

29. (Previously presented) The empty and pre-filled syringes of claim 28 wherein said physical indicia represents the length of an extender which is attached to said plunger within said pre-filled syringe.

30. (Previously presented) An empty syringe and a pre-filled syringe, the syringes respectively comprising

a body having a closed forward end having a nozzle and an open rearward end, the body of each syringe having a common diameter, and including structure mountable in a common injector,

a plunger located within said body,

said empty syringe having a first capacity,

said prefilled syringe being pre-filled with an amount of fluid different than said first capacity, and

physical indicia interacting with said common injector on one said syringe indicating information related to the range of travel of an injector ram coupled to the plunger when the syringe is coupled to an injector.

31. (Previously presented) The empty and pre-filled syringes of claim 30 wherein said physical indicia represents the length of an extender which is attached to said plunger within said syringe

Evidence Appendix

None

Related Proceedings Appendix

None

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